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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,894	10/31/2003	Liang C. Dong	ARC 3244 R1	2950

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DEWIPAT INCORPORATED
P.O. BOX 1017
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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,894	DONG ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/6/04 and 7/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosure Statements dated 5/06/04 and 7/13/04.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19,21,27,32 and 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 contains the trademark/trade names NIKKOL HCO; CREMAPHORE; TWEEN; Pluronic. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe surfactants and, accordingly, the identification/description is indefinite.

Claims 19,21,33 and 37 recites that a portion of the drug formulation is dissolved, while another portion is suspended. This suspension and dissolution occurs in the same medium and

apparently without an adequate solvent. How can a drug be partially dissolved in the same medium without a solvent present in the emulsion? Clarification of this issue is required.

3. Claim 32 recites the limitation "the non-ionic surfactant" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not specify which type of surfactant is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,2,4-7,9-14,18,22,23,25-28,38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Aviv et al (USPN 5,496,811 hereafter '811). The claims are drawn to a drug formulation comprising a hydrophobic drug, an oil phase comprising a saturated fatty acid and a surfactant. The formulation has an average particle size below 1 micron.

3. The '811 patent teaches a drug formulation comprising an oil-in-water submicron emulsion comprising a hydrophobic drug, an oily phase and a surfactant/emulsifier, where the average particle size is from 0.1-0.3 microns (abstract; col. 4, lin. 45-53). The drugs are hydrophobic and include indomethacin, betaxolol or adaprolol (claims 17). The oily phase comprises saturated fatty acids such as vegetable oil and other medium chain triglycerides having carbohydrate chains of 8-12 carbons (col. 5, lin. 21-30). The surfactant is selected from

various common compounds such as polysorbates and Pluronic F68 (col. 5, lin. 65-col. 6, lin. 13). The surfactant is present in a concentration from 0.1-5% by weight of the formulation (claims). The drug is present in a concentration up to 5% by weight of the formulation (claim 18). Regarding the formation of a stable emulsion in an aqueous environment, it is the position of the Examiner that thought the reference is silent to this specific property, the drug formulation of the '811 comprises the same components, in the same concentrations producing an emulsion. Since compositions comprising the same components must perform the same way, it is the position of the Examiner that the drug formulation of the '811 patent anticipates the claims.

4. Claims 1,2,4-14,18,22,23,25-28,38 and 39 rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al (USPN 6,113,921 hereafter '921). The claims are drawn to a drug formulation comprising a hydrophobic drug, an oil phase comprising a saturated fatty acid and a surfactant. The formulation has an average particle size below 1 micron.

5. The '921 patent teaches a drug formulation comprising an oil-in-water submicron emulsion comprising a hydrophobic drug, an oily phase and a surfactant/emulsifier, where the average particle size is from 0.1-0.3 microns (col. 4, lin. 45-53). The drugs are hydrophobic and include indomethacin, betaxolol, adaprolol and hydrophobic peptides (col. 7, lin. 10-21). The oily phase comprises saturated fatty acids such as vegetable oil and other medium chain triglycerides having carbohydrate chains of 8-12 carbons (col. 5, lin. 21-30). The surfactant is selected from various common compounds such as polysorbates and Pluronic F68 (col. 5, lin. 41-col. 6, lin. 13). The surfactant is present in a concentration from 0.1-5% by weight of the formulation (claims). The drug is present in a concentration up to 5% by weight of the

formulation (claims). Regarding the formation of a stable emulsion in an aqueous environment, it is the position of the Examiner that thought the reference is silent to this specific property, the drug formulation of the '921 comprises the same components, in the same concentrations producing an emulsion. Since compositions comprising the same components must perform the same way, it is the position of the Examiner that the drug formulation of the '921 patent anticipates the claims.

6. Claims 1-6,9-31,34-36 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Yiv et al (USPN 6,245,349 hereafter '349). The claims are drawn to a drug formulation comprising a hydrophobic drug, an oil phase comprising a saturated fatty acid and a surfactant. The formulation has an average particle size below 1 micron.

7. The '349 patent discloses a drug formulation comprising an oil component, a surfactant and a drug component (abstract). The formulation can be transformed into an oil-in water emulsion for easier transportation (col. 3, lin. 18-28). The formulation comprises a saturated fatty acid such as Captex in a concentration of 42.55% and a non-ionic surfactant in a concentration of 42.35% (table 7.1). Surfactants include Pluronic poloxamers (col. 6, lin. 6-37). The drugs include amphotericin B, which has a solubility of 750 mL (col. 4, lin. 5-14). The drug formulation has an average particle size from 50-65 nm (col. 5, lin. 1-8). Regarding the improved solubility of the drug in oil rather than water, it is the position of the Examiner that such a limitation would be an inherent feature of any formulation given the same oil and surfactant components. Since the drug formulation of the '349 comprises identical non-ionic surfactants in identical ranges, along with identical saturated fatty acids in identical ranges to the

instant claims, it is the position of the Examiner that the formulation of the '349 would inherently increase the solubility of any drug over that of water. For these reasons the disclosures render the claims anticipated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER